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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,725	09/28/2000	Penny J. Stocker	G0307/7017	7328

7590 05/22/2002  
Wolf Greenfield & Sacks PC  
600 Atlantic Avenue  
Boston, MA 02210

EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

10

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/672,725

Applicant(s)

STOCKER ET AL.

Examiner

Manjunath N Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5, 14-16, 18-23, 25, 27, 29, 30, 38 and 45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-5, 14-16, 18-23, 25, 27, 29, 30, 38 and 45 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: CRP Problem Report

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 18-22, drawn to polynucleotides, classified in class 435, subclass 252.1.
- II. Claim 14, drawn to dog p-glycoprotein polypeptide, classified in class 530, subclass 350.
- III. Claims 15-16, drawn to human p-glycoprotein polypeptide, classified in class 530, subclass 350.
- IV. Claim 23, 25, drawn to a binding agent of unknown structure that binds the polypeptide, classified in class 514, subclass 789.
- V. Claim 27, drawn to a binding agent that binds to nucleic acid, classified in class 514, subclass 789.
- VI. Claims 29-30, drawn to a method of predicting bioavailability of a compound, classified in class 436, subclass 86.
- VII. Claim 38, drawn to a method for identifying a pharmacological agent useful in treatment, classified in class 436, subclass 86.
- VIII. Claim 45, drawn to a method for determining transmembrane transport of a compound by p-glycoprotein, classified in class 436, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through V are patentably distinct from each other. The polynucleotide of group I, the polypeptide of group II, the polypeptide of group III, the binding agents of groups IV and V

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each comprise amino acid sequences and nucleotide sequences and compounds of unknown chemical structure which are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group I polynucleotide to make recombinant proteins, the polypeptide to raise specific antibodies versus the use of binding compounds to modulate the activities of the polypeptide and the polynucleotide and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions I, IV, V and VI, VII, VIII are patentably distinct from each other. The polynucleotide of group I and the binding agents of groups IV and V are products which are neither used nor made in the methods of groups VI through VIII. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions II, III and VI-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used to raise specific antibodies as opposed to its use in the methods of groups VI-VIII.

Inventions VI, VII and VIII are patentably distinct from each other. The method of predicting bioavailability of a compound of group VI, the method of identifying a pharmacological agent of group VII and the method of determining transmembrane transport of a compound of group VIII are all unrelated as they comprise distinct steps, utilize different

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products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to John Amsterdam on 1-31-02 to request an oral election to the above restriction requirement, but did not result in an election being made.

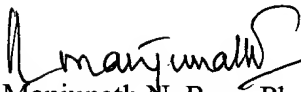
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be

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reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Manjunath N. Rao. Ph.D.  
~~May 3, 2002~~ 5/20/02